K081432

1. 510(K) SUMMARY

AUG 29 2008

Submitter: DePuy Spine, Inc.
325 Paramount Drive
Raynham, MA 02767

Contact Person: Hande Tufan
Sr. Regulatory Affairs Associate
Voice: (508) 828-3797
Fax: (508) 828-3797
E-Mail: ftufanya@dpyus.jnj.com

Date Prepared: August 25, 2008

Device Class: Class II

Classification Name: Bone grafting material
§872.3930

Classification Panel: Dental

FDA Panel Number: 76

Product Code(s): LYC

Proprietary Name: HEALOS Bone Graft Substitute

Predicate Devices: HEALOS Bone Graft Substitute (K012751, K043308)
Novabone Putty Resorbable Bone Void Filler (K051617)
NovaBone Dental Putty (K063596)
Bio-Oss Collagen Blocks (K033815)
Orthoss Resorbable Bone Void Filler (K014289)
Collagraft Strip Bone Graft Matrix (K000122)

Device Description: HEALOS is a mineralized collagen matrix processed into lyophilized strips or pads for surgical implantation. The principal components of the HEALOS Bone Graft Substitute are Type I bovine collagen and hydroxyapatite. HEALOS is approximately 30% mineral by weight.

Intended Use: HEALOS Bone Graft Material ("HEALOS") is intended to fill, augment, or reconstruct periodontal and or bony defects of the upper or lower jaw. The product provides a bone void filler that is resorbed and remodeled into new bone as part of the natural process.

Materials: The principal components of HEALOS are Type I bovine collagen and hydroxyapatite.

Performance Data: No performance standards have been established for this type of device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 29 2008

Ms. Hande Tufan
Senior Regulatory Affairs Associate
DePuy Spine, Incorporated
325 Paramount Drive
Raynham, Massachusetts 02767

Re: K081432
Trade/Device Names: HEALOS Bone Graft Substitute
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: II
Product Code: LYC, NPM
Dated: August 27, 2008
Received: August 28, 2008

Dear Mr. Tufan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

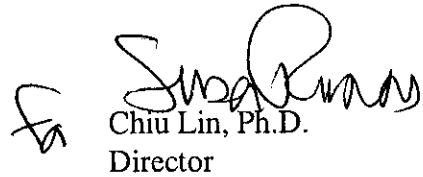
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): **K081432**

Device Name: HEALOS Bone Graft Substitute

Indications For Use:

HEALOS Bone Graft Material ("HEALOS") is intended to fill, augment, or reconstruct periodontal and or bony defects of the upper or lower jaw. The product provides a bone void filler that is resorbed and remodeled into new bone as part of the natural process.

Prescription Use ___X___ AND/OR Over-The-Counter Use ___ ___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K081432